



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Paul D. Mannheimer, et al.

Serial No.: 10/798,596

Filed: March 10, 2004

For: PULSE OXIMETER SENSOR WITH
PIECE-WISE FUNCTION

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Confirmation No.: 6350

Group Art Unit: 3768

Examiner: Winakur, Eric Frank

Atty. Docket: TYHC:0075-2/FLE/POW
P0236S-2

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Joan Deasy

**REPLY BRIEF PURSUANT TO 37 C.F.R. § 41.41 AND IN RESPONSE
TO THE EXAMINER'S ANSWER MAILED MARCH 10, 2008**

This Reply Brief is being filed pursuant to 37 C.F.R. § 41.41 and in response to the Examiner's Answer mailed on March 10, 2008. Specifically, this Reply Brief addresses the Examiner's continuing pattern of misapplying 35 U.S.C. § 112, first paragraph. In the interest of brevity, Appellants generally address below only those issues or arguments raised the Examiner's Answer that are particularly noteworthy. In view of Appellants' attempt to avoid repetition in this Reply, Appellants respectfully request that the Board consider Appellants' complete arguments set forth in the previously filed Appeal Brief, including those arguments the Examiner suggested are irrelevant.

Arguments

In Examiner's Answer, the Examiner stated that "the sole issue to resolve" is whether there is anything in the originally filed specification "that demonstrates that Applicant was in possession of the claimed subject matter at the time of the invention." *See* Examiner's Answer, page 4, line 21 – page 5, line 3. To further clarify this position, the Examiner stressed that there is not a "lack of enablement of the claimed subject matter." *Id.*, page 4, lines 17-20. Thus, it appears that the Examiner is essentially asserting that the only issue to resolve is whether the pending claims comply with the written description requirement of 35 U.S.C. § 112, first paragraph.

Regarding the written description requirement, the initial burden of proof regarding the sufficiency of the written description falls on the Examiner. *See In re Wertheim*, 541 F.2d 257, 263, 191 U.S.P.Q. 90, 97 (C.C.P.A. 1976); *see* M.P.E.P. § 2163.04. Accordingly, the Examiner must present evidence or reasons why persons skilled in the art would not recognize a description of the claimed subject matter in the applicant's disclosure. *Id.* 541 F.2d at 262, 191 U.S.P.Q. at 96. An objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012, 10 U.S.P.Q.2d 1614, 1618 (Fed. Cir. 1989); M.P.E.P. § 2163.02. The Examiner should review the claims and the entire specification, including the specific embodiments, figures, and sequence listings, to understand how applicant provides support for the various features of the claimed invention. *See* M.P.E.P. § 2163, II, A, 2. The subject matter of the claim need not be described literally (i.e., using the same terms or *in haec verba*) in order for the disclosure to satisfy the description requirement. *See* M.P.E.P. § 2163.02. In other words, the written description requirement does not require the claims to recite the same terminology used in the disclosure. The patentee may be his own lexicographer. *Ellipse Corp. v. Ford Motor Co.*, 171 U.S.P.Q. 513 (7th Cir. 1971), *aff'd*, 613 F.2d 775 (7th Cir. 1979), *cert. denied*, 446 U.S. 939 (1980). The absence of definitions or details for well-established terms or procedures should not be the basis of a rejection under 35 U.S.C. 112, first paragraph, for lack of adequate written description. *See* M.P.E.P. § 2163, II, A, 1. Information which is well known in the art need not be described in

detail in the specification. *See Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379-80, 231 U.S.P.Q. 81, 90 (Fed. Cir. 1986); *see* M.P.E.P. § 2163, II, A, 2. By disclosing in a patent application a device that inherently performs a function or has a property, operates according to a theory or has an advantage, a patent application necessarily discloses that function, theory or advantage, even though it says nothing explicit concerning it. *See* M.P.E.P. § 2163.07(a). Moreover, any information contained in any part of the application as filed, including the specification, claims and drawings, may be added to other portions of the application without introducing new matter. Accordingly, if an application as originally filed contains a claim disclosing material not disclosed in the remainder of the specification, the applicant may amend the specification to include the claimed subject matter. *In re Benno*, 768 F.2d 1340, 226 U.S.P.Q. 683 (Fed. Cir. 1985).

In the Examiner's Answer, the Examiner asserted that certain of the Appellants' arguments presented in the Appeal Brief are irrelevant because they do not pertain to the written description requirement of 35 U.S.C. § 112, first paragraph. Specifically, the Examiner stated the following:

Certain of Applicant's arguments do not appear to relate to the rejection presented above. In particular, Examiner does not contend that there is a lack of enablement of the claimed subject matter (Note Applicant's reference to *In re Wertheim*) or that the terms of the claims are inconsistent with the specification (see the reference to *Ellipse Corp. v Ford Motor Co.*). As such, these arguments are in apt.

Examiner's Answer, page 4, lines 16-20.

Appellants respectfully disagree with the Examiner's assertion that the cited legal precedent is inappropriate. Indeed, Section 2163.04 of the M.P.E.P. cites *In re Wertheim* as standing for the position that "[t]he examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims." M.P.E.P. § 2163.04. The title of Section 2163.04 of the M.P.E.P. is "Burden on the Examiner with Regard to the *Written*

Description Requirement,” which clearly indicates that the precedent is relevant with respect to the written description requirement. *Id.* (emphasis added)

Further, with regard to *Ellipse Corp. v Ford Motor Co.*, Appellants cited this case to stress that the term “functions,” as used in lines 15-17 of page 9 of the Application, may provide support for the term “formula” or the term “algorithms” recited in the present claims. In view of the Examiner’s assertion that the Examiner is not contending “that the terms of the claims are inconsistent with the specification,” it now appears that the Examiner agrees with the Appellants on this point. However, Appellants maintain it was appropriately cited because it relates to the Appellants’ assertion that a person skilled in the art would recognize a description of the invention defined by the claims.

The Examiner also asserted that “reading and analysis of page 9, lines 13-18 will lead to the conclusion that this disclosure does not provide a teaching of the sort that Applicant contends.” Examiner’s Answer, page 5, lines 4-5. Specifically, the Examiner stated the following:

The statement that “any function can be used for the formulas for determining oxygen saturation, not just the ones described” must be taken for its plain meaning in the context of the specification. Namely, that at the time of the invention, Applicant was aware that alternative functions and formulas for determining oxygen saturation than those they discussed within their specification were known and applicable for inclusion in their inventive concept. Further, Applicant was aware that development of new formulas that may have been faster or more accurate, most likely would occur, but would also likely be of a format for implementation with the disclosed inventive concept.

Examiner’s Answer, page 5, lines 5-13.

Appellants assert that this argument by the Examiner is improper and irrelevant. The Appellants’ awareness of alternative functions and formulas for determining oxygen saturation does not have any apparent correlation to the Examiner’s rejection under 35 U.S.C. § 112, first paragraph, based on the written description requirement.

The Examiner followed this argument by stating the following:

As a reminder, the invention concerns storing the formula/function on the monitor memory and storing coefficients/breakpoints to be used in the formula on the sensor memory. There is no possible interpretation of this sentence (particularly when interpreted in light of the remainder of the specification) to suggest that it is a teaching of storing the formulas on the sensor memory, as required by the claims.

Examiner's Answer, page 5, lines 14-18.

Appellants assert that the Examiner's characterization of "the invention" is improper. Indeed, it is improper for the Examiner to make such an assertion as fact without support for the assertion. Additionally, the Examiner's assertion that the quoted sentence can only be interpreted as suggested by the Examiner is clearly a conclusory argument.

Further, the Examiner stated the following:

The paragraph continues with the statement that, "For a limited sensor memory, the function representation may be compressed. Any representation of a function could be used." Although Applicant argues that these sentences show possession of the claimed subject matter (they are the only sentences in the entire specification that could remotely be interpreted in this manner), Applicant's position is not supported by the remainder of the specification, which clearly sets forth that the sensor memory is for storing coefficients and breakpoints, not formulas.

Examiner's Answer, page 5, line 19 – page 6, line 3.

Appellants assert that the Examiner has provided no legal precedent for the apparent assertion that *all* of a specification must be directed to supporting each claim. Indeed, Appellants assert that no such legal precedent exists and that the sentences relied upon by the Appellants are sufficient to meet the written description requirement for the present claims. Appellants reiterate that the cited sentences of the specification make a direct correlation between the compression of the *function* and a limited *sensor memory*. Accordingly, Appellants assert that, in context, a reasonable interpretation of the text quoted from the specification would suggest that the functions are stored on the limited sensor memory and may be compressed to facilitate their storage.

The Examiner also stated that at the time the application was filed, "including a memory in a sensor that would be discarded after use by one or only a few patients could add significantly to the cost of the sensor." Examiner's Answer, page 6, lines 6-7. Appellants assert that this argument could just as easily be considered as supporting the Appellants' position. Indeed, the cost of memory at the time of filing the application may explain why the sensor memory would be smaller and require compression of the functions to store them on the sensor memory. However, Appellants assert that this argument by the Examiner is irrelevant and has no apparent correlation to the written description requirement. Indeed, Appellants assert that cost has never been a consideration for the written description requirement.

For each of the reasons set forth above, Appellants respectfully request that the Board overturn the Examiner's rejection of claims 1-7, 9-26 and 46-53.

Conclusion

In addition to the present arguments, Appellants rely upon *all* of the reasons advanced in the Appeal Brief, and respectfully request that the Board carefully review the claims in view of these arguments and indicate the allowability of the claimed subject matter.

Respectfully submitted,

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